

**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Poonam SOLOTRA, et al.

Serial No.: 10/086,184

Group No.: 1637

Filed: February 27, 2002

Examiner: C. Wilder

For: SPECIES-SPECIFIC PCR ASSAY FOR DETECTION OF LEISHMANIA  
DONOVANI IN CLINICAL SAMPLES OF KALA-AZAR AND POST KALA-  
AZAR DERMAL LEISHMANIASIS

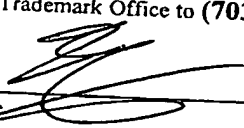
Attorney Docket No.: U 013891-8

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450**ATTENTION: OLLIE PERSON**

Reg. No. 25,858

**CERTIFICATE OF MAILING/TRANSMISSION (37 CFR 1.8a)**

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**☐ deposited with the United States Postal Service  
with sufficient postage as first class mail in an  
envelope addressed to the Commissioner for  
Patents, P. O. Box 1450, Alexandria, VA 22313-  
1450Date: November 8, 2004**FACSIMILE**☒ transmitted by facsimile to the Patent and  
Trademark Office to (703) 308-6642Signature William R. Evans

-type or print name of person certifying)

**Best Available Copy**

Practitioner's Docket No. U 013891-8

PATENT

Optional Customer No. Bar Code



00140

PATENT TRADEMARK OFFICE

**COMBINED DECLARATION AND POWER OF ATTORNEY**  
 (ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
 CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type:

(check one applicable item below)

☒ original  
☐ design

NOTE: With the exception of a supplemental oath or declaration submitted in a response, a supplemental oath or declaration is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. Section 714.16, 7<sup>th</sup> Ed.

☐ supplemental

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.

☐ national stage of PCT

NOTE: If one of the following 3 items apply, then complete and also check **ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P**.

NOTE: See 37 C.F.R. Section 1.63(d) (continued prosecution application) for use of a prior nonprovisional application declaration in the continuation or divisional application being filed on behalf of the same or fewer of the inventors named in the prior application.

☐ divisional  
☐ continuation

NOTE: Where an application discloses and claims subject matter not disclosed in the prior application, on a continuation or divisional application names an inventor not named in the prior application, a continuation-in-part application must be filed under 37 C.F.R. Section 1.53(b) (application filing requirements-nonprovisional application).

☐ continuation-in-part (C-I-P).

**INVENTORSHIP IDENTIFICATION**

**WARNING:** If the inventors are each not the inventor of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

**TITLE OF INVENTION**

Species-specific PCR Assay for detection of Leishmania donovani in clinical samples of Kala-Azar and post Kala-Azar Dermal Leishmaniasis

**SPECIFICATION IDENTIFICATION**

The specification of which:

(complete (a), (b), or (c))

(a) ☐ is attached hereto.

**NOTE:** The following combinations of information supplied in an oath or declaration filed on the application filing date with a specification are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:

"(1) name of inventor(s), and reference to an attached specification which is both attached to this oath or declaration at the time of execution and submitted with the oath or declaration on filing;

"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or

"(3) name of inventor(s), and title which was on the specification as filed."

Notice of July 13, 1995 (1/177 O.G. 60).

(b) ☒ was filed on February 27, 2002, ☒ as Application No. 10/086,184  
☐ and was amended on \_\_\_\_\_ (if applicable).

**NOTE:** Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. Section 1.67.

**NOTE:** The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:

(A) application number (consisting of the series code and the serial number, e.g., 08/123,456);  
 (B) serial number and filing date;  
 (C) attorney docket number which was on the specification as filed;  
 (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or  
 (E) title which was on the specification as filed and accompanied by a cover letter adequately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 601.01(a), 7th ed.

- (c) ☐ was described and claimed in PCT International Application No. \_\_\_\_\_ filed on \_\_\_\_\_ and as amended under PCT Article 19 on \_\_\_\_\_ (if any).

### SUPPLEMENTAL DECLARATION (37 C.F.R. Section 1.67(b))

(complete the following where a supplemental declaration is being submitted)

- ☐ I hereby declare that the subject matter of the

- ☐ attached amendment  
☐ amendment filed on \_\_\_\_\_

was part of my/our invention and was invented before the filing date of the original application, above identified, for such invention.

### ACKNOWLEDGMENT OF REVIEW OF PRACTICES AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56.

(also check the following items, if desired)

- ☐ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and

- ☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. Section 1.98.

### PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))

NOTE: 37 C.F.R. § 1.55 Claim for foreign priority.

"(a) An applicant in a nonprovisional application may claim the benefit of the filing date of one or more prior foreign applications under the conditions specified in 35 U.S.C. 119(a) through (d) and (f), 172, and 365(a) and (b).

(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(f), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 315 and § 1.323.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

- (d) ☒ no such applications have been filed.  
 (e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

**PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS  
 (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION  
 AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(e)-(f)**

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING DAY, MONTH, YEAR	PRIORITY CLAIMED UNDER 35 U.S.C. 119
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

# CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. Section 119(e))

**NOTE:** 35 U.S.C. 119(e)(1) requires that a nonprovisional application be filed within twelve months of the filing date of the provisional application for the nonprovisional application to claim the benefit of the filing date of the provisional application. Under 35 U.S.C. 21(b) and 119(e)(3), if this twelve-month period expires on a non-business day, it is extended to expire on the next business day.

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

**PROVISIONAL APPLICATION NUMBER**

**FILING DATE**

## CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. SECTION 120

- [ ] The claim for the benefit of any such applications are set forth in the attached  
**ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY  
FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P)  
APPLICATION.**

**ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

**NOTE:** If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete **ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION** for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. Section 120.

## POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(List name and registration number)

JOSEPH H. HANDELMAN, 26179

JOHN RICHARDS, 31053

RICHARD J. STREIT, 25765

PETER D. GALLOWAY, 27885

RICHARD P. BERG, 28145

JULIAN H. COHEN, 20302

WILLIAM R. EVANS, 25858

JANET I. CORD, 33778

CLIFFORD I. MASS, 30046

CYNTHIA R. MILLER, 34674

(Check the following item, if applicable)

- ☐ I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.
- ☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

NOTE: "Special care should be taken in continuation or divisional applications to ensure that any change of correspondence address in a prior application is reflected in the continuation or divisional application. For example, where a copy of the oath or declaration from the prior application is submitted for a continuation or divisional application filed under 37 CFR 1.53(b) and the copy of the oath or declaration from the prior application designates an old correspondence address, the Office may not recognize, in the continuation or divisional application, the change of correspondence address made during the prosecution of the prior application. Applicant is required to identify the change of correspondence address in the continuation or divisional application to ensure that communications from the Office are mailed to the current correspondence address. 37 CFR 1.43(d)(4)." Section 601.03, M.P.E.P., 7th Ed.

SEND CORRESPONDENCE TO

Ladas & Parry  
25 West 61<sup>st</sup> Street  
New York, N.Y. 10023

DIRECT TELEPHONE CALLS TO:

(Name and telephone number)

Clifford J. Mass  
(212) 708-1890

(complete the following if applicable)

Since this filing is a ☐ continuation ☐ divisional there is attached hereto a Change of Correspondence Address so that there will be no question as to where the PTO should direct all correspondence.

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

**NOTE:** Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

**NOTE:** Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 C.F.R. Section 1.63(a)(3).

**NOTE:** Inventors may execute separate declarations/oaths provided each declaration/oath sets forth all the inventors. Section 1.63(a)(3) requires that a declaration/oath, inter alia, identify each inventor and prohibit the execution of separate declarations/oaths which each sets forth only the name of the executing inventor. 62 Fed. Reg. 53,137, 53,142, October 10, 1997.

## Full name of sole or first inventor

ROOSEN  SALOTRA  
(Given Name) (Middle Initial or Name) Family (Or Last Name)

Inventor's signature (X)

Date (X) Country of Citizenship India

Residence C 145, Sarvodaya Enclave, New Delhi 110017, India

Post Office Address (Same as above)

## Full name of second joint inventor, if any

Gannascan  SREENIVAS  
(Given Name) (Middle Initial or Name) Family (Or Last Name)

Inventor's signature (X)

Date (X) NOV 5 2004 Country of Citizenship India

Residence C 145, Sarvodaya Enclave, New Delhi 110017, India

Post Office Address (Same as above)

## Full name of third joint inventor, if any

Gregory P POQUE  
(Given Name) (Middle Initial or Name) Family (Or Last Name)

Inventor's signature (X)

Date (X) Country of Citizenship United States of America

Residence 419 Trillick Ct., Vacaville, California 95638

Post Office Address (Same as above)



(check proper box(es) for any of the following added page(s)  
that form a part of this declaration)

☒ Signature for fourth and subsequent joint inventors. Number of pages added 1

\*\*\*

☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added \_\_\_\_\_

\*\*\*

☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. Section 1.47. Number of pages added \_\_\_\_\_

\*\*\*

☐ Added page for signature by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 C.F.R. Section 1.47)

\*\*\*

☐ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.

☐ Number of pages added \_\_\_\_\_

\*\*\*

☐ Authorization of practitioner(s) to accept and follow instructions from representative.

(If no further pages form a part of this Declaration,  
then end this Declaration with this page and check the following item)

☐ This declaration ends with this page.

Practitioner's Docket No. U 013891-8**ADDED PAGE TO COMBINED DECLARATION AND POWER OF  
ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS**

Full name of fourth joint inventor, if any

Hiralal  
(Given Name)  
(Middle Initial or Name)NABHASI  
Family (Or Last Name)Inventor's signature ☒Date ☒

Country of Citizenship

United States of AmericaResidence 8504 Potomac School Terrace, Potomac, Maryland 20854Post Office Address (Same as above)

Full name of fifth joint inventor, if any

  
(Given Name)  
(Middle Initial or Name)  
Family (Or Last Name)

Inventor's signature

Date

Country of Citizenship

Residence

Post Office Address

Full name of sixth joint inventor, if any

  
(Given Name)  
(Middle Initial or Name)  
Family (Or Last Name)

Inventor's signature

Date

Country of Citizenship

Residence

Post Office Address

(Added Page to Combined Declaration and Power of Attorney for Signature by Fourth and Subsequent Inventors  
page 1 of 3) 4-2